



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2015-0388; FRL-9933-30]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 30 chemical substances which were the subject of premanufacture notices (PMNs). Nine of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture (including import) or process any of these 30 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This rule is effective on *[insert date 60 days after date of publication in the Federal Register]*. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on *[insert date 14 days after date of publication in the Federal Register]*.

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before *[insert*

*date 30 days after date of publication in the **Federal Register***] (see Unit VI. of the **SUPPLEMENTARY INFORMATION**). If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [*insert date 30 days after date of publication in the **Federal Register***], EPA will withdraw the relevant sections of this direct final rule before its effective date.

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2015-0388, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: *moss.kenneth@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders

under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. What Action is the Agency Taking?

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture,

or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376)(FRL-3658-5). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same

SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 30 chemical substances that are the subject of these SNURs, EPA considered relevant information

about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 30 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order or the basis for the TSCA non-section 5(e) SNURs (i.e., SNURs without TSCA section 5(e) consent orders).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes 8 PMN substances that are subject to “risk-based” consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities

associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called “TSCA section 5(e) SNURs” on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The TSCA section 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

In addition, this rule includes one SNUR on a PMN substance that is subject to an “exposure-based” consent order under TSCA section 5(e)(1)(A)(ii)(II), wherein EPA determined that the PMN substance is expected to be produced in substantial quantities, and that there may either be significant or substantial human exposure and/or the PMN substance may enter the environment in substantial quantities. The TSCA section 5(e) consent order requires submission of certain test data to EPA before the manufacturer may exceed a specified production volume. These SNURs designate as a “significant new use” the absence of the protective measures or exceedance of the production volume limit required in the TSCA section 5(e) consent order.

This rule also includes SNURs on 21 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a “significant new use.” These so-called “TSCA non-section 5(e) SNURs” are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a

“significant new use” in all TSCA non-section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

PMN Numbers P-12-69, P-12-70, and P-12-520

Chemical name: Fatty acids compound with cyclohexanamine (generic) (P-12-69 and 70) and Fatty acids amine salt (generic) (P-12-0520).

CAS numbers: Claimed Confidential.

Effective date of TSCA section 5(e) consent order: February 11, 2015.

Basis for TSCA section 5(e) consent order: The PMNs states that the generic (non-confidential) use of the substances will be as a lubricity additive (P-12-69 and P-12-70) and a chemical component for fuel additives (P-12-520). Based on structure-activity relationship (SAR) analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms to occur at concentrations that exceed 52 parts per billion (ppb) (P-12-69), 4 ppb (P-12-70) and 180 ppb (P-12-520) of the PMN substances in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMNs, exceed releases from the use described in the PMNs. For the uses described in the

PMNs, environmental releases did not exceed 52 ppb, 4 ppb, or 180 ppb, respectively, for more than 20 days per year. The consent order for these PMN substances was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the uncontrolled manufacture, processing, distribution in commerce, use and disposal may present an unreasonable risk to the environment. To protect against these risks, the consent order requires manufacturing, processing, or use of the substance for the specific confidential uses stated in the PMNs. The SNUR designates as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of a fish early life-stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnia chronic toxicity test (OPPTS 850.1300) would help characterize the environmental effects of the PMN substances. Testing should be done on P-12-69 only. The submitter has agreed not to exceed a confidential volume limit without performing this testing.

CFR citations: CFR 721.10852 (P-12-69 and P-12-70) and 40 CFR 721.10856 (P-12-520).

PMN Number P-12-169

Chemical name: Fluoro-modified acrylic copolymer (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: March 19, 2015.

Basis for TSCA section 5(e) consent order: The PMN states that the use of the substance will be as a substrate wetting and leveling agent for organic solvent-based paints and inks. EPA has concerns for potential incineration or other decomposition products of the PMN substance. These fluorinated decomposition products may be released to the environment

from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, which suggests that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including perfluorooctanoic acid (PFOA) and other perfluorinated alkyls, including the presumed environmental degradant. The order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products. To protect against these exposures and risks, the consent order requires:

1. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substance may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into a Material Safety Data Sheet (MSDS), within 90 days.

2. Submission of certain physical/chemical property and environmental fate testing on a related PMN substance prior to exceeding the confidential production volume limits as specified in the consent order of the PMN substance.

3. Recording and reporting of certain fluorinated impurities in the starting raw

material and the initially isolated intermediates; and manufacture of the PMN substance not to exceed the maximum established impurity levels of certain fluorinated impurities. The SNUR designates as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain physical/chemical property and environmental fate testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substance and its degradation products. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. Further, EPA has identified certain toxicity and environmental fate testing described in the Pended Testing section of the Preamble to the Order that would help characterize the possible effects of the PMN substance. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10853.

PMN Number P-12-351

Chemical name: Siloxanes and Silicones, alkyl, alkyl propoxy ethyl, methyl octyl, alkyl polyfluorooctyl (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: March 19, 2015.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a coating additive. EPA has concerns for potential incineration or other decomposition products of the PMN substance. These fluorinated decomposition products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, which suggests that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including perfluorooctanoic acid (PFOA) and other perfluorinated alkyls, including the presumed environmental degradant. The order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products. To protect against these exposures and risks, the consent order requires:

1. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substances may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into a MSDS, within 90 days.
2. Submission of certain physical/chemical property and environmental fate

testing on a related PMN substance prior to exceeding the confidential production volume limits as specified in the consent order of the PMN substances.

3. Recording and reporting of certain fluorinated impurities in the starting raw material and the initially isolated intermediates; and manufacture of the PMN substances not to exceed the maximum established impurity levels of certain fluorinated impurities. The SNUR designates as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain physical/chemical property and environmental fate testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substances and their degradation products. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. Further, EPA has identified certain toxicity and environmental fate testing described in the Pended Testing section of the Preamble to the Order that would help characterize the effects of the PMN substances. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10854.

PMN Number P-12-450 and P-12-451

Chemical name: Partially fluorinated alcohol, reaction products with phosphorus oxide (P_2O_5), amine salts (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: March 16, 2015.

Basis for TSCA section 5(e) consent order: The PMNs state that the generic (non-confidential) use of the substances will be as coating additives and surface active agents. EPA has concerns for potential incineration or other decomposition products of the PMN substances. These perfluorinated decomposition products may be released to the environment from incomplete incineration of the PMN substances at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, which suggests that, under some conditions, the PMN substances could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including perfluorooctanoic acid (PFOA) and other perfluorinated alkyls, including the presumed environmental degradant. The order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products. To protect against these exposures and risks, the consent order requires:

1. Risk notification. If as a result of the test data required, the company becomes aware that the PMN substances may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into a MSDS, within 90 days.

2. Submission of certain physical/chemical property and environmental fate testing on a related PMN substance prior to exceeding the confidential production volume limits as specified in the consent order of the PMN substances.

3. Recording and reporting of certain fluorinated impurities in the starting raw material and the initially isolated intermediates; and manufacture of the PMN substances not to exceed the maximum established impurity levels of certain fluorinated impurities. The SNUR designates as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain physical/chemical property and environmental fate testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substances and their degradation products. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. Further, EPA has identified certain toxicity and environmental fate testing described in the Pended Testing section of the Preamble to the Order that would help characterize the effects of the PMN substances. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will

remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10855.

PMN Number P-13-292

Chemical name: Organophosphorus polymer (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: February 13, 2015.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as an additive for polymers. Using available exposure information from the public literature (i.e., measured values for similar substances in house dust in homes), and certain assumptions for mouthing behavior by young children, EPA identified concerns for potential exposure to the general population. However, there is uncertainty about the risk from this scenario due to the absence of hazard data on the PMN substance itself and information on the ability for the PMN substance to migrate or leach out of certain consumer products. Consumer exposure is possible if the PMN migrates from these products or decomposes to form dust particles that can be inhaled or ingested. Analogous chemicals, including Tris(2-chloroethyl)phosphate (TCEP) and Tris(1,3-dichloro-2 propyl) phosphate (TDCPP), can be found in household dust, and are widespread in the environment. Assuming similar use patterns over time, the PMN substance may be expected to display similar exposure patterns. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(II), based on a finding that this substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there

may be significant (or substantial) human exposure to the substances and their potential degradation products. To address potential exposures and hazards, the consent order requires certain testing by certain confidential production volume limits.

Recommended testing: EPA has determined that the results of certain physical/chemical property, toxicity, potential for migration from products, and dermal and other absorption testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substance. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

CFR citation: 40 CFR 721.10857.

PMN Number P-13-305

Chemical name: Fluorinated acid alkylester (generic).

CAS number: Claimed confidential.

Effective date of TSCA section 5(e) consent order: February 27, 2015.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate. EPA has concerns that the PMN substance will persist in the environment, could bioaccumulate, and be toxic (“PBT”) to humans, other mammals, and birds. EPA’s concerns are based on data on the PMN substance, and analogy to perfluorobutanoic acid (PFBA), PFOA, perfluorooctanol sulfonate (PFOS), and other analogs. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that this substance may present an unreasonable risk of injury to the environment and human health. To protect against these exposures and risks, the consent order requires:

1. Risk notification. If the company becomes aware that the PMN substances may present a risk of injury to human health or the environment, the company must incorporate this new information, and any information on methods for protecting against such risk into a Material Safety Data Sheet (MSDS), within 90 days.
2. Use of personal protective equipment including impervious gloves and a National Institute of Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 10, when there is potential exposure.
3. Establishment and use of a hazard communication program, including health hazard precautionary statements on each label and the MSDS.
4. Use of the PMN substance only as a chemical intermediate. Any chemical substance manufactured using the PMN substance may contain residuals of the PMN substance at a certain maximum level.
5. Recover and convert, capture (destroy), recycle, or reuse the substance at a certain overall efficiency when the PMN substance is used as an intermediate in accordance with the provisions.
6. Not use the PMN substance in consumer products.

The SNUR designates as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain toxicity, metabolism and pharmacokinetics testing described in the Pended Testing section of the Preamble to the Order would help characterize the human health effects of the PMN substance. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing,

distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10858.

PMN Number P-14-563

Chemical name: Quaternary alkyl methyl amine ethoxylate methyl chloride (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a cleaner/degreaser. Based on submitted test data on the PMN substance as well as SAR analysis of test data on analogous cationic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 29 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 29 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 29 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10859.

PMN Number P-14-756

Chemical name: Substituted carboxamide (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a material for highly dispersive use in consumer products and component of a consumer product. Based on submitted test data on the PMN substance as well as SAR analysis of test data on analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 3 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 3 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) and would help characterize the environmental effects of the PMN substance.

CFR Citation: 40 CFR 721. 10860.

PMN Number P-14-804

Chemical name: Phosphoric acid, sodium titanium (4+) salt (3:1:2).

CAS number: 22239-24-3.

Basis for action: The PMN states that the substance will be used as a component in anode material in sealed batteries. Based on SAR analysis of test data on analogous inorganic phosphates and titanium compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 4 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 4 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10861.

PMN Numbers P-15-1, P-15-2, P-15-3, P-15-4, P-15-5, and P-15-6

Chemical names: Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate (P-15-1); Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, sodium salt (P-15-2); Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, potassium salt (P-15-3); Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, ammonium salt (P-15-4); Ethanol, 2-

amino-, compd. with 2-methyloxirane polymer with oxirane monohexadecyl ether phosphate (P-15-5); and Ethanol, 2,2'2",-nitrilotris-, compd. with 2-methyloxirane polymer with oxirane monohexadecyl ether phosphate (P-15-6).

CAS numbers: 73361-29-2 (P-15-1); 151688-56-1 (P-15-2); 1456802-88-2 (P-15-3); 1456802-89-3 (P-15-4); 1456803-12-5 (P-15-5); and 1456803-14-7 (P-15-6).

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as inert surfactants in pesticide formulations. Based on SAR analysis of test data on analogous anionic surfactant compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb in aggregate of the PMN substances in surface waters. As described in the PMNs, releases of the substances are not expected to result in surface water concentrations exceeding 18 ppb in aggregate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in aggregate releases to surface waters exceeding 18 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test (OPPTS Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. The recommended testing may be performed on any one of the 6 PMN chemicals.

CFR Citation: 40 CFR 721.10862.

PMN Number P-15-25

Chemical name: Nitrile amine (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a site-limited chemical intermediate. Based on submitted test data on the PMN substance as well as SAR analysis of test data on analogous neutral organic compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10863.

PMN Number P-15-26

Chemical name: 1,3-Propanediamine, N1,N1-alkyl (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a friction modifier. Based on submitted test data on an analogous substance as

well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 32 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 32 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 32 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (Organisation for Economic Co-operation and Development (OECD) Test Guideline 23) be consulted to facilitate solubility in the test media, because of the PMN substance's low water solubility.

CFR Citation: 40 CFR 721.10864.

PMN Number P-15-36

Chemical name: 2-Pyridinecarboxylic acid, 4,5,6-trichloro-.

CAS number: 496849-77-5.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on SAR analysis of test data on analogous

pyridine-alpha-acids and neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 30 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 30 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 30 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010), an algal toxicity test (OCSPP Test Guideline 850.4500), and the aerobic/anaerobic transformation in soil test (OECD 307) would help characterize the environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10865.

PMN Number P-15-61

Chemical name: Imidazoliurn, polymer with cyclic anhydride and alkenoic acid, alkali salt (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a leather chemical. Based on SAR analysis of test data on analogous polyanionic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 200 ppb of the PMN substance in surface waters for greater

than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 200 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a ready biodegradability test (OPPTS Test Guideline 835.3110), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10866.

PMN Number P-15-98

Chemical name: Hydrochlorofluorocarbon (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate in the production of a hydrofluorocarbon (HFC). Based on SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic

organisms may occur at concentrations that exceed 99 ppb of the PMN substance in surface waters. Further, based on test data on analogous organohalogen compounds, there were health concerns regarding anesthesia at high inhalation doses from exposure to the PMN substance via dermal and inhalation exposure. As described in the PMN, exposure is expected to be minimal due to use of adequate dermal and respiratory personal protection equipment and releases of the substance are not expected to result in surface water concentrations exceeding 99 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface waters exceeding 99 ppb, or any use without the use of NIOSH-certified organic vapor cartridge respirator with an assigned protection factor of at least 25, or any use other than as a chemical intermediate may result in serious human health or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a an acute inhalation toxicity test (OPPTS Test Guideline 870.1300), fish acute toxicity test (OPPTS Test Guideline 850.1075), an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010), and algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10867.

PMN Number P-15-136

Chemical name: Alkylalkenoic acid copolymer (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an encapsulating polymer. Based on test data on analogous high molecular weight polymers, EPA identified concerns for lung toxicity. As described in the PMN, EPA does not expect significant worker inhalation exposure due to no domestic manufacture, and the substance is not manufactured, processed, or used in the form of a powder. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any domestic manufacture of the substance or any import, processing, or use of the substance in the form of a powder may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test with a 60-day holding period (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR Citation: 40 CFR 721.10868.

PMN Number P-15-141

Chemical name: D-Glucitol, alkylamino-N-acyl derivs. (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the substance will be used as a surfactant in cleaning products and liquid soaps. Based on test data on the PMN substance, as well as SAR analysis of test data on analogous nonionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 14 ppb. Therefore, EPA has not

determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 14 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a ready biodegradability test (OECD Test Guideline 301) would help characterize the environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10869.

PMN Number P-15-150

Chemical name: Cyclohexanedicarboxylic acid, dialkyl ester (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an adjuvant used in reaction processes. Based on SAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 10 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 10 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 10 ppb may cause significant adverse environmental effects.

Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10870.

PMN Number P-15-221

Chemical name: Isocyanate prepolymer (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as ingredient in an industrial adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for irritation and sensitization to the skin and lungs. As described in the PMN, EPA does not expect significant occupational dermal or inhalation exposure due to use of adequate personal protective equipment and consumer exposures are not expected as the PMN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure, or any use in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR Citation: 40 CFR 721.10871.

PMN Number P-15-242

Chemical name: Heteropolycyclic, polymer with alkanedioic acid, di-alkenoate (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a coating resin. Based on test data on analogous acrylates, EPA identified concerns for oncogenicity, developmental toxicity, liver and kidney toxicity, sensitization, irritation, and acute toxicity. Further, based on SAR analysis of test data on analogous acrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 120 ppb of the PMN substance in surface waters. As described in the PMN, occupational exposures are expected to be minimal due to the use of impervious gloves, goggles, and NIOSH-certified particulate respirators with an APF of at least 10. Further, releases of the substance are not expected to result in surface water concentrations exceeding 120 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without use of impervious gloves and goggles, when there is a potential dermal exposure; use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10, where there

is a potential for inhalation exposures; or any use of the substance that results in releases to surface waters exceeding 120 ppb may result in significant adverse health and environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(ii), and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OPPTS 870.3650); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.10872.

PMN Number P-15-247

Chemical name: Methylene diisocyanate polymer with diols and triols (generic).

CAS number: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an industrial adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization and lung and mucous membrane irritation based on the isocyanate moiety. As described in the PMN, EPA does not expect significant occupational dermal or inhalation exposure due to use of adequate personal protective equipment and consumer exposures are not expected as the PMN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance

without a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure, or any use in consumer products, may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR Citation: 40 CFR 721.10873.

PMN Number P-15-278

Chemical name: Polymer of isophorone diisocyanate and amine-terminated propoxylatedpolyol (generic).

CAS numbers: Claimed confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a crosslinker. Based on analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PMN substance when the average molecular weight is below 2500 daltons and any molecular weight species is below 1000 daltons. EPA does not expect significant exposures from the form of the PMN substance as described in the PMN. Therefore, EPA has not determined that the proposed manufacture of the substance may present an unreasonable risk. EPA has determined, however, that any manufacture of the PMN substance with an average molecular weight of below 2500 daltons and any molecular weight species below 1000

daltons may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR Citation: 40 CFR 721.10874.

V. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for 9 of the 30 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit VI.).

In the other 21 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.

- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

- EPA will be able to regulate prospective manufacturers or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA section 5(e), 5(f), 6, or 7.

- EPA will ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is *[insert date 60 days after date of publication in the*

Federal Register] without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before *[insert date 30 days after date of publication in the Federal Register]*.

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before *[insert date 30 days after date of publication in the Federal Register]*, EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies. EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage

in a use that has been identified as a significant new use. However, TSCA section 5(e) consent orders have been issued for 9 of the 30 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which would be designated as significant new uses. The identities of 22 of the 30 chemical substances subject to this rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Therefore, EPA designates [*insert date of publication in the **Federal Register***] as the cutoff date for determining whether the new use is ongoing. Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the **Federal Register** document of April 24, 1990 for a more detailed discussion of the cutoff date for ongoing uses.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).

2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is

required to submit each study before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40

CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1).

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission

would be necessary to determine whether that higher volume would be a significant new use.

X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2015-0388.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

This action establishes SNURs for several new chemical substances that were the subject of PMNs, or TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this action.

This action is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit XI. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

XIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: September 21, 2015.

Maria J. Doa

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

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Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9--[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following sections in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * *	* * *
Significant New Uses of Chemical Substances	
* * *	* * *
721.10852	2070-0012
721.10853	2070-0012
721.10854	2070-0012
721.10855	2070-0012
721.10856	2070-0012
721.10857	2070-0012

721.10858	2070-0012
721.10859	2070-0012
721.10860	2070-0012
721.10861	2070-0012
721.10862	2070-0012
721.10863	2070-0012
721.10864	2070-0012
721.10865	2070-0012
721.10866	2070-0012
721.10867	2070-0012
721.10868	2070-0012
721.10869	2070-0012
721.10870	2070-0012
721.10871	2070-0012
721.10872	2070-0012
721.10873	2070-0012
721.10874	2070-0012
* * * * *	

* * * *

PART 721--[AMENDED]

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

4. Add § 721.10852 to subpart E to read as follows:

§ 721.10852 Fatty acids compound with cyclohexanamine (generic).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as fatty acids compound with cyclohexanamine (PMNs P-12-69 and P-12-70) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

5. Add § 721.10853 to subpart E to read as follows:

§ 721.10853 Fluoro-modified acrylic copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoro-modified acrylic copolymer (PMN P-

12-169) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication program.* A significant new use of the substance is any manner or method of manufacture or processing associated with any use of the substance without providing risk notification as follows:

(A) If as a result of the test data required under the TSCA section 5(e) consent order for the substance, the employer becomes aware that the substances may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (a significant new use is any use other than as allowed by the section 5(e) consent order, which includes analysis and reporting and limitations of maximum

impurity levels of certain fluorinated impurities), and (q).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (f), and (i) are applicable to manufacturers and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

6. Add § 721.10854 to subpart E to read as follows:

§ 721.10854 Siloxanes and Silicones, alkyl, alky propoxy ethyl, methyl octyl, alkyl polyfluorooctyl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as siloxanes and silicones, alkyl, alky propoxy ethyl, methyl octyl, alkyl polyfluorooctyl (PMN P-12-351) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication program.* A significant new use of the substance is any manner or method of manufacture or processing associated with any use of the substance without providing risk notification as follows:

(A) If as a result of the test data required under the TSCA section 5(e) consent order for the substance, the employer becomes aware that the substances may present a risk of injury to human health or the environment, the employer must incorporate this

new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (a significant new use is any use other than as allowed by the section 5(e) consent order, which includes analysis and reporting and limitations of maximum impurity levels of certain fluorinated impurities), and (q).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (f), and (i) are applicable to manufacturers and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

7. Add § 721.10855 to subpart E to read as follows:

§ 721.10855 Partially fluorinated alcohol, reaction products with phosphorus oxide (P₂O₅) amine salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as partially fluorinated alcohol, reaction products with phosphorus oxide (P₂O₅), amine salts (PMNs P-12-450 and P-12-451) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication program.* A significant new use of the substances is any manner or method of manufacture or processing associated with any use of the substances without providing risk notification as follows:

(A) If as a result of the test data required under the TSCA section 5(e) consent order for the substances, the employer becomes aware that the substances may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance(s) are not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance(s) are reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance(s) from the employer, or who have received the PMN substance(s) from the employer within 5 years from the date the employer becomes aware of the new

information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (a significant new use is any use other than as allowed by the section 5(e) consent order, which includes analysis and reporting and limitations of maximum impurity levels of certain fluorinated impurities), and (q).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (f), and (i) are applicable to manufacturers and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b) (1) apply to paragraph (a)(2)(ii) of this section.

8. Add § 721.10856 to subpart E to read as follows:

§ 721.10856 Fatty acids amine salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acids amine salt (PMN P-12-520) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in

§ 721.80(k) and (q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

9. Add § 721.10857 to subpart E to read as follows:

§ 721.10857 Organophosphorus polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as organophosphorus polymer (PMN P-13-292) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to this section.

10. Add § 721.10858 to subpart E to read as follows:

§ 721.10858 Fluorinated acid alkylester (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as fluorinated acid alkylester (PMN P-13-305) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), (b)(concentration set at 1.0 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4): Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(ii) *Hazard communication program.* Requirements as specified in § 721.72(a), (b), (c), (d), (e), (f)(concentration set at 1.0 percent), (g)(1)(The PMN substance may cause central nervous system depression, liver effects, endocrine effects), (g)(2), and (g)(5). In addition a significant new use of the substances in any manner or method of manufacture or processing associated with any use of the substances without providing risk notification as follows:

(A) If as a result of the test data required under the TSCA section 5(e) consent order for the substances, the employer becomes aware that the substances may present a risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a MSDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance(s) are not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance(s) are reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the PMN substance(s) from the employer, or who have received the PMN substance(s) from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (g) and (o). It is a significant new use for any chemical substance manufactured using the PMN substance to contain residuals of the PMN substance above the level

specified in the consent order. It is a significant new use to recover and convert, capture (destroy), recycle, or reuse the PMN substance below the overall efficiency specified in the consent order, when the PMN substance is used as an intermediate.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

11. Add § 721.10859 to subpart E to read as follows:

§ 721.10859 Quaternary alkyl methyl amine ethoxylate methyl chloride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as quaternary alkyl methyl amine ethoxylate methyl chloride (PMN P-14-563) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=29).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

12. Add § 721.10860 to subpart E to read as follows:

§ 721.10860 Substituted carboxamide (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted carboxamide (PMN P-14-756) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=3).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

13. Add § 721.10861 to subpart E to read as follows:

§ 721.10861 Phosphoric acid, sodium titanium (4+) salt (3:1:2).

(a) Chemical substance and significant new uses subject to reporting. (1) The

chemical substance identified as phosphoric acid, sodium titanium (4+) salt (3:1:2) (PMN P-14-804; CAS No. 22239-24-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=4).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

14. Add § 721.10862 to subpart E to read as follows:

§ 721.10862 Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate; Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, sodium salt; Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, potassium salt; Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, ammonium salt; Ethanol, 2-amino-, compd. with 2-methyloxirane polymer with oxirane monohexadecyl ether phosphate; and Ethanol, 2,2'2'',-nitrilotris-, compd. with 2-methyloxirane polymer with oxirane monohexadecyl ether phosphate.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The

chemical substances identified as oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate (P-15-1; CAS No. 73361-29-2); oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, sodium salt (P-15-2; CAS No. 151688-56-1); oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, potassium salt (P-15-3; CAS No. 1456802-88-2); oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, ammonium salt (P-15-4; CAS No. 1456802-89-3); ethanol, 2-amino-, compd. with 2-methyloxirane polymer with oxirane monohexadecyl ether phosphate (P-15-5; CAS No. 1456803-12-5); and ethanol, 2,2'2",-nitrilotris-, compd. with 2-methyloxirane polymer with oxirane monohexadecyl ether phosphate (PMN P-15-6; CAS No. 1456803-14-7) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=18 in aggregate).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

15. Add § 721.10863 to subpart E to read as follows:

§ 721.10863 Nitrile amine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as nitrile amine (PMN P-15-25) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

16. Add § 721.10864 to subpart E to read as follows:

§ 721.10864 1,3-propanediamine, N1, N1-alkyl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 1,3-propanediamine, N1, N1-alkyl (PMN P-15-26) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=32).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

17. Add § 721.10865 to subpart E to read as follows:

§ 721.10865 2-Pyridinecarboxylic acid, 4,5,6-trichloro-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-pyridinecarboxylic acid, 4,5,6-trichloro- (PMN P-15-36; CAS No. 496849-77-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=30).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

18. Add § 721.10866 to subpart E to read as follows:

§ 721.10866 Imidazoliurn, polymer with cyclic anhydride and alkenoic acid, alkali salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as imidazoliurn, polymer with cyclic anhydride and alkenoic acid, alkali salt (PMN P-15-61) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial commercial, and consumer activities.* Requirements as specified in § 721.80 (j).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

19. Add § 721.10867 to subpart E to read as follows:

§ 721.10867 Hydrochlorofluorocarbon (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hydrochlorofluorocarbon. (PMN P-15-98) is

subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 40 CFR 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (b)(concentration set at 1.0 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 25 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(ii) *Industrial commercial, and consumer activities.* Requirements as specified in § 721.80 (g).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=99).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

20. Add § 721.10868 to subpart E to read as follows:

§ 721.10868 Alkylalkenoic acid copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as alkylalkenoic acid copolymer (PMN P-15-136) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (f), (v)(1), (w)(1), and (x)(1).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

21. Add § 721.10869 to subpart E to read as follows:

§ 721.10869 D-Glucitol, alkylamino-N-acyl derivs. (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as D-glucitol, alkylamino-N-acyl derivs. (PMN P-15-141) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=14).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

22. Add § 721.10870 to subpart E to read as follows:

§ 721.10870 Cyclohexanedicarboxylic acid, dialkyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as cyclohexanedicarboxylic acid, dialkyl ester (PMN P-15-150) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (N=10).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

23. Add § 721.10871 to subpart E to read as follows:

§ 721.10871 Isocyanate prepolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as isocyanate prepolymer (PMN P-15-221) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(C) NIOSH-certified negative pressure (demand) supplied-air respirator with a full facepiece.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

24. Add § 721.10872 to subpart E to read as follows:

§ 721.10872 Heteropolycyclic, polymer with alkanedioic acid, di-alkenoate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heteropolycyclic, polymer with alkanedioic acid, di-alkenoate (PMN P-15-242) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(2)(iii), (a)(3), (a)(4), (a)(6)(ii), (a)(6)(v), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(ii) *Release to water.* Requirements as specified 721.90 (a)(4), (b)(4), and (c)(4) (N=120).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

25. Add § 721.10873 to subpart E to read as follows:

§ 721.10873 Methylene diisocyanate polymer with diols and triols (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as methylene diisocyanate polymer with diols and triols (PMN P-15-247) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(C) NIOSH-certified negative pressure (demand) supplied-air respirator with a full facepiece.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

26. Add § 721.10874 to subpart E to read as follows:

§ 721.10874 Polymer of isophorone diisocyanate and amine-terminated propoxylatedpolyol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polymer of isophorone diisocyanate and amine-terminated propoxylatedpolyol (PMN P-15-278) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. The significant new use is manufacture of the substance where the average molecular weight is below 2500 daltons and where any molecular weight species is below 1000 daltons.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2015-24846 Filed: 10/1/2015 08:45 am; Publication Date: 10/2/2015]